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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/259,758	03/01/1999	SUSAN K. BROWN-SKROBOT	VTN-0388	5657

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

AS-2

Office Action Summary	Application No.	Applicant(s)	
	09/259,758	BROWN-SKROBOT ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,18-31,33-43 and 45-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,18-31,33-43 and 45-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This final office action is in response to the amendment received on 11/16/2001

Claim Objections

1. Claims 45-46 are objected to because of the following informalities: Claims 45-46 depends on a cancelled claim 44. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-12, 18-31, 33-43, and 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) and further in view of Shalaby et al (U.S.P.N. 5,422,068), Dunn et al (U.S.P.N. 4,910,942), and Heyl et al (U.S.P.N. 5,431,879).

With respect to claims 51-52, and 2-13; Clark et al teaches a process and an apparatus for sterilizing a medical device (col.1, lines 7-20), which includes the following concepts: subjecting contact lens (col.7, lines 1-3) to UV in the range of 240 to 280 NM (col.3, lines 60-63), wherein the contact lens is in a hermitically sealed container (col.8, line 33), and further the container is transmissive to at least 50% of UV (abstract, lines 3-5, col.3, lines 53-54, lines 59-63. Thus, such citations include any percentage value for transmissivity. For example, 80% or 50% or the like) in substantially all directions (figure 8); subjecting a medical device (col.1, lines 13-15) to UV radiation (col.3, lines 60-62) in the range of 240-280 NM (col.3, line 3) using energy value at least 3.9 mj/cm^2 (col.8, lines 10-12). In addition; Clark et al teaches a sterility assurance level of at 10^-6 (abstract, line 21). Furthermore; all the energy values in the claims full within the teaching of Clark et al energy value range (col.8, lines 10-12), which contains a specific low range value and a specific high range value. Clark et al goes on to further teach of specific energy values within this range (col.8, lines 11-12). Moreover; Clark et al discloses the following concepts: the application of UV radiation to spores (col.9, lines

50-53); the usage of at least one pulsed radiation source (col.6, line 26 and col.3, lines 51-56; various time ranges for applying the radiation which all the values in the claim falls into (col.8, lines 12-19); more than 1 radiation source (col.6, line 26); radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims); flash lamps comprises a reflector and a lamp (figure 1, 22) wherein the fluence of each is at the focal plane of reflector (figure 1, 22:20); pulsed radiation source in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37); the contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%); and container comprises an aqueous solution (col.8, line 4).

With respect to claims 52, 2-12, and 18-19; Clark et al does not teach the following concepts: D values specific for Bacillus Stearothermophilus ATCC 7953; radiation is produced by a laser; determining the D value of Bacillus Stearothermophilus ATCC 7953 by a mathematical relationship; and a specific transmissivity value for the container. However; Clark et al does provide examples of applying UV radiation to various types of spores (examples 1 and 2) wherein the D values of the spores are intrinsically represented by achieving a sterility of assurance level of at least 10^-6.

With respect to claims 20-31, and 33-41; Clark et al teaches a process and an apparatus for sterilizing contact lens (col.1, lines 7-20 and col.4, lines 55-57) comprising the following concepts: modifying radiation from a radiation source to eliminate

wavelengths which would damage contact lens (col.3, line 36, line 38, and col.4, lines 55-57); container comprises a non-preserved aqueous solution (col.1, lines 10-13); container is transmissive to radiation in substantially all directions (col.6, lines 45-55); the use of packages or containers is disclosed made of thermoplastics (col.3, line 48 and col.1, lines 29-30); at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25); an apparatus is light-tight (col.8, lines 38-39); and forming a contact lens (col.5, lines 43-61).

With respect to claims 20-31, and 33-41; Clark et al does not teach the following concepts: D values specific for Bacillus Stearothermophilus ATCC 7953; radiation is produced by a laser; determining the D value of Bacillus Stearothermophilus ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; and container comprises a lid and a bowl.

With respect to claims 42-43, 45-50, and 53-54; Clark et al teaches a process and an apparatus for sterilizing a medical device (col.1, lines 7-20), which includes the following concepts: at least one reflector directs radiation from each radiation source to a treatment area (figure 1, 18:22); treatment area is located at the focal plane of reflector (figure 8, 18:22 and the unlabeled rays). In addition; Clark et al teaches of a capacitance and a potential (col.10, lines 1-8), however; Clark et al does not provide specific values for capacitance and for potential. Since the claims are trying to exactly accomplish what Clark et al teaches then it is intrinsic in the apparatus of Clark et al to encompass the same values for capacitance and a potential. Furthermore, Clark et al

discloses the use of reflectors with enhanced reflection (col.6, lines 42-44); and the reflector minimizes the non-ultraviolet radiation reaching the medical device (col.6, lines 45-48).

With respect to claims 42-43, 45-50, and 53-54; Clark et al does not teach the following concepts: D values specific for Bacillus Stearothermophilus ATCC 7953; radiation is produced by a laser; determining the D value of Bacillus Stearothermophilus ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 52-54; Matner et al teaches of a method for determining the efficacy of a sterilization cycle (col.1, lines 7-8) wherein it is known to use Bacillus Stearothermophilus ATCC 7935 to verify how efficient a sterilization cycle is (col.2, lines 35-39).

Matner et al does not teach the following: D values specific for Bacillus Stearothermophilus ATCC 7953; forming contact lens: radiation is produced by a laser; determining the D value of Bacillus Stearothermophilus ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 52-54; Shalaby et al teaches of methods of sterilization comprising, col.2, lines 20-22; radiation source, col.2, lines 20-48; wherein the concept

of D-value is and its importance to sterility assurance level is explained, col.3, lines 28-65; also the D-values of Bacillus Stearothermophilus are shown, columns 6-11 (examples 1-6). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values, col.3, lines 46-57.

Shalaby et al does not teach the following: radiation is produced by a laser; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 13, 54, 31, 33, 42, 45, and 47, Dunn et al teaches of a method for sterilizing packaging of medical devices (col.1, lines 17-21) wherein a laser is used (col.2, lines 17-22); a container with at least 50% transmissivity to UV light is used (col.6, lines 15-20); and specific range values for capacitance and for potential (col.22, lines 23-25); and radiation sources are wired in series (figure 3, 358).

Dunn et al does not teach of container comprising a lid and a bowl.

With respect to claim 33, Heyl et al teaches of a method for sterilizing and disinfecting, col.1, lines11-16, wherein the container comprises a lid and a bowl, col.9, lines 35-37. Thus, it would have been obvious and one having ordinary skill in the art would have been motivated to combine the teaching of Clark et al for a system and a method of sterilizing a medical device by applying UV radiation to spores with another art-known in the determining the efficacy of sterilization cycles by specifically using Bacillus Stearothermophilus (ATCC 7935) bacterial spore for the known and expected

results that the bacterial spore is recognized as the most resistant form of bacterial life and further all tests for determining sterilization efficacy use it (Matner et al, col.5, lines 53-60).

Response to Arguments

6. Applicant's arguments filed 11/16/2001 have been fully considered but they are not persuasive.

On page 9 of the response, lines 10-17; applicant argues that Clark et al discloses a contact lens container, which includes foil, and a blister. However, this is only one embodiment. Clark et al teaches that any type of contact lens package can be sterilized using UV radiation. See col.7, lines 1-3. Furthermore, Clark et al discloses a contact lens container, which is transmissive to radiation. See col.3, lines 59-63. However, Clark et al does not provide a specific range values. Since Clark et al is achieving the same sterility as the applicant, then Clark et al apparatus and method must intrinsically includes a contact lens container, which is transmissive to at least 50% of radiation. Also, Clark et al discloses that a contact lens container is sterilized in substantially all directions. See figure 8.

On page 10 of the response, lines 1-2; applicant argues that Clark et al does not teach the specific range for the capacitance values. However, since Clark et al is achieving the same sterility as the applicant, then Clark et al apparatus must intrinsically includes a capacitance of 80 to 160 microfarad. In addition, this range of capacitance

values is not unknown in the prior art and is within the scope of a person skilled in the art to determine the capacitance range of values to achieve the required level of sterility. Furthermore, Dunn et al does teach of a capacitance values. See col.22, lines 23-25.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

8. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
January 24, 2002

Robert J. Warden, Sr.

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